

## § 520.2122

per 20 pounds of body weight to a maximum of 5 capsules with the dosage repeated at 3 day intervals until a satisfactory therapeutic response is observed. A maintenance dosage is then administered consisting of 1 capsule per 40 pounds of body weight, with a minimum of 1 capsule per 40 pounds of body weight, with a minimum of 1 capsule, given every 3 days, or 7 days, or longer, as required to maintain improvement or an asymptomatic condition. For dogs under 20 pounds of body weight, the small capsules are administered orally at a dosage level of 1 per 5 pounds of body weight with a minimum of 1 capsule which dosage is repeated at 3 day intervals until a satisfactory response is observed then a maintenance regimen is initiated with 1 capsule per 10 pounds of body weight, minimum of 1 capsule, every 3 days, or 7 days, or longer as required to maintain continued improvement or an asymptomatic condition.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 52 FR 7832, Mar. 13, 1987; 52 FR 9756, Mar. 26, 1987]

## § 520.2122 Spectinomycin dihydrochloride oral solution.

(a) *Specifications.* The spectinomycin dihydrochloride pentahydrate used in manufacturing the drug is the antibiotic substance produced by growth of *Streptomyces flavopersicus* (var. Abbott) or the same antibiotic substance produced by any other means. The drug is packaged as an aqueous solution containing 50 milligrams of spectinomycin activity per milliliter.

(b) *Sponsors.* (1) See No. 059130 in § 510.600(c) of this chapter.

(2) See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used for the treatment and control of infectious bacterial enteritis (white scours) associated with *E. coli* in pigs under 4 weeks of age.

(2) It is administered orally at the rate of 50 milligrams per 10 pounds body weight twice daily for 3 to 5 days.

(3) Do not administer to pigs over 15 pounds body weight or over 4 weeks of

## 21 CFR Ch. I (4–1–02 Edition)

age. Do not administer within 21 days of slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 45 FR 56798, Aug. 26, 1980; 46 FR 60570, Dec. 11, 1981; 61 FR 5506, Feb. 13, 1996; 65 FR 45877, July 26, 2000]

## § 520.2123 Spectinomycin dihydrochloride pentahydrate oral dosage forms.

### § 520.2123a Spectinomycin dihydrochloride pentahydrate tablets.

(a) *Specifications.* The spectinomycin dihydrochloride pentahydrate used in manufacturing the drug is the antibiotic substance produced by growth of *Streptomyces flavopersicus* (var. Abbott) or the same antibiotic substance produced by any other means.

(b) *Sponsor.* See No. 061133 in § 510.600(c) of this chapter.

(c) *Special considerations.* The quantities of spectinomycin cited in this section refer to the equivalent weight of base activity for the drug.

(d) *Conditions of use.* (1) The tablets are administered orally to dogs in the treatment of infectious diarrhea and gastroenteritis caused by organisms susceptible to spectinomycin.

(2) The drug is administered orally to provide 10 milligrams per pound of body weight twice daily. The tablets may be placed in the animal's mouth or crushed and administered in milk or in the feed. Dosage may be continued for 4 consecutive days. Should no improvement be observed, discontinue drug and redetermine diagnosis.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 47 FR 14149, Apr. 2, 1982; 66 FR 14073, Mar. 9, 2001]

### § 520.2123b Spectinomycin dihydrochloride pentahydrate soluble powder.

(a) *Specifications.* The spectinomycin dihydrochloride pentahydrate used in manufacturing the drug is the antibiotic substance produced by growth of *Streptomyces flavopersicus* (var. Abbott) or the same antibiotic substance produced by any other means.

(b) *Sponsor.* See No. 061133 in § 510.600(c) of this chapter.

(c) *Special considerations.* The quantities of spectinomycin cited in this section refer to the equivalent weight of base activity for the drug.

(d) *Related tolerances.* See § 556.600 of this chapter.

(e) *Conditions of use.* (1) It is administered in the drinking water of growing chickens at 2 grams of spectinomycin per gallon of water as the only source of drinking water for the first 3 days of life and for 1 day following each vaccination. It is administered as an aid in the prevention or control of losses due to CRD associated with *M. gallisepticum* (PPLO). Do not administer to laying chickens. Do not administer within 5 days of slaughter.

(2) It is administered in the drinking water of floor-raised broiler chickens at 0.5 gram of spectinomycin per gallon of water as the only source of drinking water for the first 3 days of life and for 1 day following each vaccination. It is administered for increased rate of weight gain and improved feed efficiency. Do not administer to laying chickens. Do not administer within 5 days of slaughter.

(3) It is administered in drinking water of broiler chickens at 1 gram of spectinomycin per gallon of water as the only source of drinking water for the first 3 to 5 days of life as an aid in controlling infectious synovitis due to *Mycoplasma synoviae*. Do not administer to laying chickens. Do not administer within 5 days of slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 45 FR 56798, Aug. 26, 1980; 66 FR 14073, Mar. 9, 2001]

#### § 520.2150 Stanozolol oral dosage forms.

##### § 520.2150a Stanozolol tablets.

(a) *Specifications.* Each tablet contains 2 milligrams of stanozolol.

(b) *Sponsor.* No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) Used as an anabolic steroid treatment in dogs and cats.

(2) Administered orally to cats and small breeds of dogs, ½ to 1 tablet twice daily for several weeks; to large breeds of dogs, 1 to 2 tablets twice daily for several weeks. The tablets

may be crushed and administered in feed.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 46101, Oct. 6, 1975, as amended at 42 FR 36995, July 19, 1977. Redesignated at 50 FR 38114, Sept. 20, 1985, and amended at 55 FR 23076, June 6, 1990]

#### § 520.2150b Stanozolol chewable tablets.

(a) *Specifications.* Each chewable tablet contains 2 milligrams of stanozolol.

(b) *Sponsor.* No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) Used as an anabolic steroid treatment in dogs.

(2) Administered orally to small breeds of dogs, ½ to 1 tablet twice daily for several weeks; to large breeds of dogs, 1 to 2 tablets twice daily for several weeks.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[50 FR 38114, Sept. 20, 1985, as amended at 55 FR 23076, June 6, 1990]

#### § 520.2158 Streptomycin/dihydrostreptomycin oral dosage forms.

##### § 520.2158a Streptomycin sulfate oral solution.

(a) *Specifications.* Solution containing 25 percent streptomycin sulfate.

(b) *Sponsor.* See Nos. 033008 and 055462 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.610 of this chapter.

(d) *Conditions of use.* Use in drinking water as follows:

(1) *Calves and swine*—(i) *Amount.* 10 to 15 milligrams per pound (mg/pound) of body weight (1.0 to 1.5 grams per gallon).

(ii) *Indications for use.* Treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella* spp. susceptible to streptomycin.

(iii) *Limitations.* Calves: Do not administer for more than 5 days. Swine: Do not administer for more than 4 days. Prepare fresh solution daily. Calves: Withdraw 2 days before slaughter. As sole source of streptomycin. Warning: Certain strains of bacteria